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EXAMINER

KRASS, FREDERICK F

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/224,781
Filing Date: January 04, 1999
Appellant(s): LIBIN, BARRY M.

James V. Costigan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 22, 2007, appealing from the Office action mailed September 09, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,236,699	LIBIN	8-1993
GB 2160 099 A	TAKAOKA, YOGO	12-1985
EP 0 670 711 B1	FORWARD ET AL.	11-1993

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Rejection 1.

Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 670 711 B1.

The prior art discloses the treatment of fungal infections, including oral *Candida*, with a combination of triclosan and nisin. The compositions may be in mouthwash (liquid) or gel (semi-solid) form. See paragraph 0015. See also working examples 1, 4, 6, 9, 10, 13 and 25.

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Rejection 2.

Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2 160 099

A.

The prior art discloses the use of triclosan, either in solution with alcohol or water, or as an ointment, to treat athlete's foot fungus (see page 1, lines 35-38).

Rejection 3.

Claims 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Libin (USP 5,236,699) in view of EP 0 670 711 B1.

The primary reference discloses mouthrinses comprising a combination of triclosan and cetylpyridinium chloride, which are used to inhibit plaque formation and to treat periodontitis (column 4, lines 57-60). It differs from the instant claims in its silence regarding the treatment of fungal infections.

Triclosan and cetylpyridinium chloride are both known to be active against the oral fungus *Candida*. See the secondary reference at paragraph 0009, and also at working example 25 (bridging pages 13 and 14). The reference also recognizes that these agents are equally useful for inhibiting plaque (paragraph 0043). It differs from the instant claims insofar as it does not specify the use of the two agents together.

It would have been obvious to have administered mouthrinses comprising triclosan and cetylpyridinium chloride to oral *Candida* patients, motivated by the desire to inhibit plaque as taught by the primary reference, while simultaneously treating the *Candida* infection as taught by the secondary reference.¹

(10) Response to Argument

Rejection 1.

Appellant takes the following position:

This ground of rejection is in error because the cited reference requires the presence of additional active materials that are excluded by the terms of claims 23-25. The amended claims, which included the recitation 'consisting essentially of', exclude the use of the polypeptide antibiotic nisin which is an essential component of the '711 compositions. For this reason, the amended claims are not anticipated by the '711 patent. (Brief, page 3).

Explaining the basis for arriving at this conclusion, appellant notes:

Nisin is a polypeptide antibiotic according to the '711 patent and therefore would have a profound and material effect on the properties of the compositions of the '711 patent. The phrase 'consisting essentially of', when used with triclosan, excludes other active materials because the specification and claims clearly contemplate the use of triclosan alone as the sole antifungal agent. Pages 9-11 of the original specification disclosed a number of compositions with triclosan as the sole active ingredient. Under the rationale of *In re Janakirama-Rao*, 137 USP 893, 895-6 (CCPA 1963, claims 23-25 should not be read as including nisin because this interpretation of the claims would be contrary to the applicants specification. (Brief, page 4).

The examiner does not agree with appellant's characterization of the facts.

¹ The examiner notes that this rejection could have been alternatively constructed such that the claims were rejected over EP 0 670 711 B1 in view of Libin, with the rationale for using triclosan and cetylpyridinium chloride together arising from their disclosure as individual anti-*Candida* agents and motivated by the desire to take advantage of the superior absorption and retention properties recognized for the combination from the teachings of the secondary reference. By either construction, however, the ultimate issue becomes whether nisin would be excluded by the transitional phrase "consisting essentially of".

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There is no evidence of record to support appellant's allegation that nisin has a "profound and material effect on the properties" on the prior art compositions. To the contrary, the prior art clearly states that nisin merely maintains the anti-*Candida* activity of triclosan and cetylpyridinium chloride. See page 2, lines 50-52. See also the disclosure at page 14, lines 27-39 which plainly notes that "although there is no evidence to suggest any degree of synergy between Ambicin N and any of cetylpyridinium chloride, chlorhexidine or triclosan, the data also shows that there is no reduction in the activity of either agent in the presence of the other; ie, there is mutual compatability." (emphasis added).

Nor does the examiner agree with appellant's characterization of the law.

The Janakirama-Rao court clearly held at page 894-5 that the burden to demonstrate any material differences resides with appellant, not the examiner:

We find no error in this rejection. The reference shows an optical glass in which silica and bismuth and cadmium oxides are present within the claimed proportions. The appellant states that other ingredients are present in the Armistead composition so that the glass of Armistead is an entirely different glass than appellant's. *In what respects its characteristics are different the appellant has not set forth.* The appellant has cited Ex parte Davis et al., 80 USPQ 448, but we do not see the other ingredients of the Armistead glass *materially* effect the *basic* characteristics of appellant's glass. Since there is no showing of properties of the claimed optical glasses as patentably different from those of Armistead, this rejection... will be sustained. (Emphasis original).

The court continues at pages 895-6:

[I]t is our opinion that appellant is in no position to urge that they are so restricted by the phrase 'consisting essentially of' that they define subject matter patentable over Armistead merely because the glasses of the reference contain some *modifying* ingredients in addition to silica, cadmium oxide and bismuth oxide. So may appellant's glasses. The word 'essentially' opens the claims to the inclusion of ingredients which do *not* materially affect the *basic* and novel characteristics of appellant's compositions as defined in the balance of the claim, according to applicable law. But no basic or novel characteristic to be so affected can be deduced from the disclosure and none was shown in brief or argument. We therefore find that the board was correct in holding that there is no showing of properties patentably distinguishing appellant's claimed glasses from those of the reference. (Italics original; underlining added).

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Appellant has not i) pointed out in what respects the characteristics of the compositions of the prior art are materially different than those of the claims nor ii) shown what basic or novel characteristic is affected by the inclusion of nisin. That nisin may be “essential” to the prior art disclosure, or that appellant may use triclosan as the “sole antifungal agent”, is irrelevant to this legal inquiry. As discussed supra, the inclusion of nisin does not in any way alter the basic antifungal activity of triclosan.

Appellant states that claim 24 is not anticipated by the ‘711 patent because it does not disclose the use of a solubilizer. (Brief, page 4). The examiner can find no factual basis to support this allegation. The prior art uses water alone (working examples 1-8) or in combination with ethanol (working examples 9-13 and 16) as a solvent (solubilizer); additionally the surfactants disclosed at page 3, lines 15-29 would have a solublizing function as well.

Appellant states that claim 25 is not anticipated by the ‘711 patent because that patent does not disclose a semi-solid composition. Again, the examiner can find no factual basis to support this allegation. The gels disclosed at page 1, lines 53, and the toothpastes prepared in working examples 1-8, are semisolids.

Rejection 2.

Appellant takes the following position:

This ground of rejection is also error because the cited reference requires the presence of additional active materials that are excluded by the terms of claims 23-25. The claims, which include the recitation 'consisting essentially of', exclude the use of urea which the '099 patent describes as a necessary 'horny substance softening agent.' For this reason the amended claims are not anticipated by the '711 patent. (Brief, page 5).

Explaining the basis for arriving at this conclusion, appellant notes:

Urea is present in all of the compositions of the '099 patent for the purpose of softening horny skin substances and therefore the presence of this material has a physiological effect on the properties of the '099 patent. The phrase 'consisting essentially of' when used with triclosan excludes urea because the specification and claims of the present application clearly contemplate the use of triclosan alone as the sole antifungal agent. Pages 9-11 of the original specification disclosed a number of compositions with triclosan as the sole active ingredient. As noted above, under the rationale of *In re Janakirama-Rao*, 137 USP 893, 895-6 (CCPA 1963, the presence of urea should not be read into the text of claims 23-25 based on applicant's specification. (Brief, pages 5 and 6).

Again, appellant has not fulfilled his burden of showing that the addition of urea would materially affect the basic and novel characteristics of the claimed invention. The urea component of the prior art is added to increase penetration in areas such as the foot or palm, where athlete's foot resides in the thick horny layer and thus is particularly difficult to reach. See, e.g., the prior art at page 1, lines 7-18. This in no way changes the basic antifungal characteristics of the compositions, however; it simply increases their reach. Moreover, applicant's claims are not limited to the treatment of any particular fungus, nor any particular site on the body. Indeed, the instant specification instead specifies athlete's foot as one of the fungal infections to be treated by the instant methods (page 3, line 23).

The assertions made on page 6 of the Brief concerning claims 24 and 25 of the “ ’711 ” patent are not understood since those same assertions were made previously on page 4 of the Brief. Insofar as appellant apparently meant to discuss the ‘099’ patent, the examiner again can find no factual basis to support these assertions. Claim 3 of the reference recites ointments, which are semi-solids; furthermore, the prior art uses ethanol and water to dissolve (solubilize) triclosan: see page 2, lines 50-52.

Rejection 3.

Appellant takes the following position:

The ‘711 patent always uses nisin in combination with the triclosan component and nisin is not a cationic agent. In addition, the ‘711 patent does not show the use of triclosan alone or in combination with a cationic agent for treating a fungal condition. The text of the ‘711 patent mentions that nisin is always present and that it may be used either with cetylpyridinium chloride or triclosan. The nisin component is always present and the transitional phrase ‘consisting essentially of’ is properly used to exclude this component because based on the text of the ‘11 patent one would not be directed to exclude nisin as it is a key component having a material effect on the properties of the composition...

There is no teaching or direction in either of the cited references which tells the skilled artisan to delete the nisin component of the ‘711 patent or to use the combination of a cationic agent and triclosan to treat a fungal infection. (Brief, page 7).

Again, the examiner does not agree with appellant’s characterization of the facts. The prior art clearly teaches that each of cetylpyridinium chloride and triclosan individually has activity against *Candida*. See the prior art disclosure at the passage bridging page 13, lines 39 to page 14, line 40; note the unambiguous use of the word “individually” at page 14, line 37. Since they are both antifungal agents, this clearly provides a reasonable expectation of success for

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using the primary reference compositions, which contain those same active agents, to treat *Candida* infections.

Moreover, the examiner again does not agree with appellant's characterization of the law. The prior art need not provide any teaching or direction which tells the skilled artisan to delete the nisin component; rather, the issue at hand is whether including nisin in the instant compositions would materially affect their basic and novel characteristics. As discussed supra, the facts of record demonstrate that nisin has no effect on the basic antifungal activities of either triclosan or cetylpyridinium chloride.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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(12) Conclusion

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



Frederick Krass
Primary Examiner
Art Unit 1614

Conferees:



Michael Woodward
Supervisory Patent Examiner
Art Unit 1615



Ardin Marschel
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Art Unit 1614

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